

June 25 GTF Meeting Minutes – DRAFT

The Washington State Board of Health Genetics Task Force (GTF) convened its fourth meeting on June 25, 2002 at the Holiday Inn Express and Suites in SeaTac, WA. Linda Lake, Genetics Task Force Chair, called the meeting to order at 9:40 a.m.

The following GTF members attended the meeting:

Helen McGough	Phil Bereano	Wylie Burke
Peter Byers	Ty Thorsen	Maureen Callaghan
Suzanne Plemmons	Mellani Hughes	Maxine Hayes
Ron Scott	Robin Bennett	Amanda DuBois
Linda Lake	Joe Finkbonner	Julie Sanford-Hanna

The following Board of Health staff members attended the meeting:

Don Sloma, Desiree Robinson, Jennifer Dodd, Candi Wines

Chair Lake introduced the minutes from the April 12, 2002 meeting. There was one request to correct the attendance record on the minutes.

Announcements

Don Sloma reported that the Legislature is still very interested in the GTF's work and is waiting for the report.

Ty Thorsen requested a change to the agenda. He suggested providing time at end of each subcommittee report to give the public a chance to comment. The Task Force adopted this change.

Chair Lake reviewed the purpose of today's meeting. She stated that the goal is to come to agreement on the content of the final report. The intention is not necessarily to get agreement on the conclusions and recommendations, but to agree on the content of the report including majority and minority opinions on each issue. Discussion at today's meeting will focus on the subcommittee reports and be directed at reaching a conclusion on the information from those reports to be presented in the final report to the Legislature. The purpose of the September 4th GTF meeting includes the final review of the report to the Legislature.

Subcommittee 1 Report

Dr. Ron Scott provided an overview of the report from Subcommittee One: The Use of Genetic Information in Health Care. A copy of the report was provided in the meeting binders and on the web site.

Discussion

The discussion of this Subcommittee report included the following comments:

- Consider changing the language of the report where necessary throughout the report to broaden its scope beyond DNA analysis to include other forms of genetic testing such as chromosome analysis and protein/metabolic tests. Dr. Wylie Burke agreed to provide specific definitions of “genetic information/genetic test” from the NIH DOE Task Force on Genetic Testing and the SACGT reports. Professor Phil Bereano suggested using the CRG definition of “genetic information” as outlined in the Model Law provided by SC2. The GTF agreed that this subcommittee (SC1) could work out an appropriate definition via email for this report. Chair Lake recommend that the members review the GTF Working Glossary for previously proposed definitions of ‘genetic information’ and ‘genetic testing’. Dr. Ron Scott proposed the following language: “genetic information obtained from laboratory testing”. Dr. Burke commented that this excludes family history information and noted that other task forces have specifically excluded family history information because their charge was only to consider testing issues. She suggested that the GTF consider if family history information can be used to discriminate against a person and therefore if it should be included in the definition of genetic information adopted by this group.
- Consider changing the subcommittee report where necessary to include language related to the risk of discrimination. The added language should reflect the fact that there is a risk of discrimination based on genetic information and also acknowledge the lack of evidence presented to the GTF at the previous meetings. One suggestion included the following language: “While there is risk of discrimination based upon the use of DNA technology in the above scenarios, the Task Force [received] no evidence of such discrimination.”
- The issue of access to tests was discussed and it was suggested that a mention of the cost of testing and access to services be included in the “Other” section at the end of the report.
- It was suggested that a comment regarding the possibility that patents could inhibit research be added to the “Findings” under the “Incentives for further research and development on the use of DNA to promote public health, safety and welfare” section in Part I.
- A task force member recommended adding a comment regarding disability rights and the potential for prenatal/reproductive use of genetic information to discriminate against those with disabilities to the “Findings” under the “The incidence of discriminatory actions based upon genetic information” section in Part II.
- The majority of the GTF voted to remove recommendation number 1 under the “Strategies to safeguard civil rights and privacy related to genetic information” section of Part III; however there was no conclusion regarding whether it should be included as a minority opinion; the GTF agreed to examine the degree of protections afforded to all medical records before making a decision about the inclusion of this recommendation as a minority opinion.
- It was suggested that the statement regarding an obligation to disclose genetic information be stricken from the report.

- It was suggested that a finding regarding the cost of and access to genetic testing services be added to the “Additional Findings, Conclusions and Recommendations” section.

Break 11:10

Subcommittee 2 Report

Dr. Maxine Hayes provided an overview of the report from Subcommittee Two: State Mandated DNA Collection and Testing – the Newborn Screening Program and the Criminal DNA Database. A copy of the report was provided in the meeting binders and on the web site. Dr. Hayes acknowledged Mike Glass for his assistance with preparing the report.

Discussion

The discussion of this Subcommittee report included the following comments:

- It was suggested that the subcommittee add a comment regarding tort law and whether it covers disclosure of the newborn screening information.
- It was suggested that the report include a statement regarding the need to re-examine privacy issues if the number of tests mandated or offered by the state increases. The task force agreed that a broader statement regarding the dynamic nature of the issues being examined should be made in the report with a recommendation that the issues may need to be reconsidered in the future as things change.
- It was noted that RCW 70.02 does provide specific remedies for the misuse of NBS samples and therefore the report should indicate that state laws does provide specific remedies in this case.
- The task force discussed the recommendation of destroying the criminal DNA samples after the testing and data collection are complete; it was agreed that this recommendation would be included as a minority opinion.
- It was suggested that the language in conclusion number one in the “Remedies to compensate individuals for inappropriate use of genetic information” section in Part II be revised to state that “state law does not provide *specific* remedies”
- It was suggested that a discussion about registering complaints and/or monitoring for violations be added to the report.

Break 12:30

Subcommittee 3 Report

Dr. Peter Byers provided an overview of the report from Subcommittee Three: The Use of Genetic Information in Research. A copy of the report was provided in the meeting binders and on the web site.

Discussion

The discussion of this subcommittee report included the following comments:

- A task force member suggested that the subcommittee add a discussion about the distinction between research and medical information and how conclusions/recommendations may differ based on this distinction. It was suggested that such a discussion elaborate on what RCW 42.48 and RCW 70.02 do and don't do with respect to each type of information.
- It was suggested that the report reflect the numerous ways that genetic information is used or created and communicated to subjects in research studies. Five different situations were noted: 1) existing genetic information is used for research; it was noted that RCW 70.02 protects existing information if it is considered health care information; 2) research activities create genetic information via an experimental genetic test and the result is not disclosed to the subject; the task force felt that it was important to answer the question of what, if any, laws apply to this type of information?; 3) research activities create genetic information via a certified genetic test and results are disclosed to the subject or made a part of the medical record; the task force concluded that at this point the result becomes health care information and is protected under RCW 70.02; 4) genetic information is obtained using non-certified genetic tests and the results are disclosed to the subject; he asked what if any laws apply to this information?; 5) research is either overseen by an IRB or it is not, this depends on the funding/regulatory agency.
- It was suggested that the report include a more detailed discussion and analysis of the ADA and recent Supreme Court decisions reflecting the Court's interpretation and scope of the ADA. A task force member also recommended that the report explain exactly what protections the WA Law Against Discrimination provides and whether or not it covers any gap(s) left by the ADA.
- The subcommittee agreed to rewrite conclusion #3 under the "The incidence of discriminatory actions based upon genetic information from research activities" section to include specific reference to WAC 284.43.720, RCW 49.60 and the ADA.
- The task force asked the subcommittee to add a comment regarding the de-identification of data/genetic information/tissue samples and how this benefits/harms researchers and subjects.
- It was requested that the subcommittee rewrite conclusion #4 under the "Strategies to safeguard civil rights and privacy related to genetic information" section so that the meaning of "waivers of consent" is clear and the conclusion makes a substantive statement about the benefits/harms of the waiver process.
- The task force did not reach agreement on recommendation #1 under the "Strategies to safeguard civil rights and privacy related to genetic information" section. The subcommittee agreed to remove recommendation #4 and to write recommendation #5 as a minority opinion.

- The subcommittee agreed to revise recommendation #2 under the “Incentives for further research and development on the use of DNA to promote public health, safety and welfare” section

Break 3:15

Subcommittee 4 Report

Mellani Hughes provided an overview of the report from Subcommittee Four: The Use of Genetic Information for Social Purposes such as Health, Life, and Disability Insurance and Employment. A copy of the report was provided in the meeting binders and on the web site.

Discussion

The discussion of this subcommittee report included the following comments:

- The task force recommended that the subcommittee expand on statement number three under “Findings” in the “The incidence of discriminatory actions based upon genetic information”. For example, there are at least two ways that this statement can be intended – insurance companies use genetic information to calculate population-based life expectancy rates, etc. or it could also mean that a variety of factors could be construed as ‘genetic’ and this is highly dependent on the definition of genetic information.
- It was agreed that finding number six in the “The incidence of discriminatory actions based upon genetic information” section would be expressed as a minority opinion in the final report.
- The subcommittee agreed to add a list of specific statutes that support conclusion number one in the “The incidence of discriminatory actions based upon genetic information” section.
- It was suggested that conclusion number two in the “The incidence of discriminatory actions based upon genetic information” section be revised to include a separate discussion of state and federal laws. It was also suggested that the subcommittee consider adding a statement about the non-disability nature of some genetic information to this conclusion.
- The subcommittee agreed to remove recommendation number one in the “The incidence of discriminatory actions based upon genetic information” section and to take more time to review RCW 49.60, the ADA, HIPAA, and RCW 70.02.
- The task force suggested that the subcommittee include in the report a discussion regarding whether there are adequate protections in current law that pertain to access to and use and disclosure of genetic information by employers.
- The subcommittee agreed to add a statement about Washington’s law prohibiting cousins from marrying.
- It was suggested that finding number one in the “Strategies to safeguard civil rights and privacy related to genetic information” section include a statement about the applicability of RCW 70.02 and HIPAA to employment.

- The subcommittee agreed to revise finding number four in the “Strategies to safeguard civil rights and privacy related to genetic information” section to include WAC 284.04 and remove the Graham-Leach-Bliley Act.
- Regarding conclusion number two in the “Strategies to safeguard civil rights and privacy related to genetic information” section, it was suggested that the subcommittee review the RCW pertaining to informed consent for HIV testing and to consider the circumstances under which this law was enacted.
- It was suggested that conclusion number four in the “Strategies to safeguard civil rights and privacy related to genetic information” section be removed as it is addressed in another subcommittee report.
- It was suggested that recommendation number two be rewritten to include the collection of biological samples/genetic information for insurance purposes. Specific language recommended regarding requiring informed consent included: “...where it is already allowable to collect and use genetic information for insurance purposes, an individual’s informed consent must be obtained.” Chair Lake suggested that a broad statement on requiring informed consent for genetic testing in any capacity be incorporated in to the final report.

General Discussion

Robin Bennett noted that none of the subcommittee reports addressed the issue of genetic testing in minors; Dr. Scott agreed to add this topic to his revised subcommittee report.

Chair Lake stated that the next phase is to write a complete report that fairly represents the conclusions and recommendations. The goal is to have an agreed upon language in cohesive, clear, useful report. The subcommittees will have an opportunity to revise their reports based on today’s report and then staff will combine them into one report. The final report has to be finalized by the end of the Sept 4 meeting. She noted that the staff will develop a schedule to give the whole group a chance to provide feedback on the report.

Chair Lake summarized the meeting and noted that one of the questions the subcommittees need to clearly answer in their reports is if RCW 70.02 provides sufficient protection for health care information.

Don Sloma asked task force members to consider whether the DOH NBS program draft policy would be better in rule (WAC) or as an internal DOH policy. Chair Lake commented that it is important to have a recommendation from the GTF on this issue before the Board and the DOH discuss it.

Adjourned 5:00 p.m.